

REMARKS

This amendment is responsive to the Office Action dated June 18, 2003. Applicants here amend claims 1 and 2, claims 6-7 remain cancelled (without prejudice or disclaimer), and Applicants herewith add new claims 8-13. Applicants respectfully solicit entry of and favorable consideration of the amendments and remarks set forth herein.

New claims 8-12 closely relate to the subject matter of claims 1-6 except they are set forth in method claim format. New claim 13 is directed to instructions for performing the present computer-implemented invention, as stored on a computer readable medium. Adequate support for the newly presented claims is found in the specification of the application (and the prior provisional application) as well as via principles of inherency, given the nature of the subject matter claimed.

Thus, claims 1-5 and 8-13 are presented for examination on the merits.

Claim Rejections Under 35 U.S.C. § 112

In the Office Action, the Examiner rejected claims 1-5 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. The Examiner's rejection was directed to the preamble of claim 1. Applicants have amended the preamble of claim 1 to simplify the preamble. Claim 1, as amended, does not claim a system for a particular purpose. Rather, claim 1, as amended, claims a system in accordance with the body of claim 1. Applicants have further amended claim 1 to move an antecedent basis for "IMD," which previously was in the preamble of claim 1, to the body of claim 1.

The Examiner further rejected claims 1-5 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Specifically, the Examiner stated that claim 1 is indefinite because the preamble of claim 1 indicates the external device controls the operation of the implantable (the Examiner used the word

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"implanted") medical device, and the body of claim 1 indicates the external device provides collected data to the implantable medical device, and the implantable medical device processor controls the therapy provided by the implantable medical device. The Examiner further asserted that claim 1 is indefinite because it is not clear how the external device (sensor) controls the implantable medical device.

The Examiner's rejection based upon 35 U.S.C. § 112, second paragraph, was directed to the preamble of claim 1. Applicants have amended the preamble of claim 1. Applicants submit that claim 1, as amended, particularly points out and distinctly claims the subject matter that Applicants regard as the invention.

Claim Rejection Under 35 U.S.C. § 102

In the Office Action, the Examiner rejected claims 1, 2, 4 and 5 under 35 U.S.C. § 102(b) as being anticipated by Tockman et al. (US 5,562,707). In particular, the Examiner asserted that Tockman teaches a method and apparatus to automatically optimize the pacing mode and the pacing cycle parameters of an implantable stimulating device using an optimization sequence, read as providing a dynamic closed loop self-monitoring system. According to the Examiner, the apparatus comprises a pacemaker, a micro-controller, a radio frequency (RF) telemetry link, and external sensors/monitors, including an oximeter.

Applicants respectfully traverse the rejection to the extent such rejection may be considered applicable to the amended claims.

"A single prior art reference anticipates a patent claim if it expressly or inherently describes each and every limitation set forth in the patent claim." Trintec Indus. Inc. v. Top-U.S.A. Corp., 63 USPQ2d 1597, 1599 (Fed. Cir. 2002). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Id. Tockman fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

Tockman does not disclose an external sensor module transmitting collected physiological data signals to the IMD, as recited in claim 1. On the contrary, Tockman discloses transmitting "operating parameters" to the IMD or programming to the IMD. Col. 3, lines 62-65; col. 5, lines 12-14; col. 6, lines 54-58. In particular, a programmer 42 receives signals from various sensors 44-52, but Tockman does not disclose or suggest transmitting those sensor signals to the IMD via telemetry link 40.

The Tockman sensors themselves do not transmit physiological data signals to the IMD. In fact, the Tockman sensors themselves do not transmit signals of any kind to the IMD. More particularly, the Tockman sensors do not transmit signals by a communication channel including RF signals, as recited in claim 4.

Furthermore, Tockman does not teach or suggest that a processor in the IMD processes physiological data collected by an external sensor, as recited in claim 1. Instead, Tockman discloses the IMD receiving "operating parameters" or programming from programmer 42. Col. 3, lines 62-65; col. 5, lines 12-14; col. 6, lines 54-58.

Tockman also fails to teach or suggest the IMD processor processing the physiological data to produce therapy delivery control signals in implementation of dynamic closed loop self monitoring therapy delivery, as recited in claim 1. The Tockman implanted device does not receive physiological data, and consequently the Tockman implanted device does not process physiological data in implementation of dynamic closed loop self monitoring therapy delivery, as recited in claim 1.

In view of the differences identified above, Tockman clearly fails to anticipate the features set forth in claims 1, 2, 4 and 5. For at least these reasons, the Examiner has failed to establish a *prima facie* case for anticipation of Applicants' claims 1, 2, 4 and 5 under 35 U.S.C. § 102(b). Withdrawal of these rejections is requested.

In addition, as a matter of convenience only Applicants herewith amend claim 2 to render the informal term "neuro" to the more formal - - neurological - -. Applicants respectfully assert that this minor amendment was added for convenience and not for any reason related to patentability and that, in any event, said amendment does not constitute a narrowing amendment to claim 2.

Claim Rejection Under 35 U.S.C. § 103*Prochazka in view of Salo*

In the Office Action, the Examiner rejected claims 1-5 under 35 U.S.C. § 103(a) as being unpatentable over Prochazka et al. (US 5,562,707) in view of Salo et al. (US 5,487,752). According to the Examiner, Prochazka discloses a wrist sensor and a controller for providing functional electrical stimulation to an implanted muscle microstimulator. The IMD, according to the Examiner, is a neuro stimulator, the external sensor is a wristwatch sensor, and the medical data is the pressure of muscular stress as the wrist is flexed and extended. The Examiner asserted that Prochazka discloses an implanted muscle microstimulator that uses RF signals to transmit energy and commands to the microstimulator. The Examiner further asserted that Prochazka discloses processor capability, because Prochazka teaches devices described in US 5,193,540 to Schulman, which includes control logic that the Examiner reads as a processor controlling delivery of therapy to the patient.

The Examiner asserted that Prochazka discloses the claimed invention except for the physiological data being transferred to the IMD. The Examiner cited Salo as teaching physiological monitoring using externally mounted sensors that monitor a physiological condition and transfer the physiological data signal to the sensor signal processor of the implanted device for the purpose of controlling therapy provided by the implantable medical device. According to the Examiner, it would have been obvious to one having ordinary skill in the art at the time of the invention to have used the external sensor of Salo in the Prochazka system in order to simplify the external electronics of the monitoring system by eliminating the need for the external controller to produce a control signal.

Applicants respectfully traverse the rejections.

In connection with combining references to support an assertion of obviousness, it is well established that the Examiner bears the burden of establishing a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992). In doing so, the Examiner must determine whether the prior art provides a "teaching or suggestion to one of ordinary skill in the art to make the changes that would produce"

the claimed invention. In re Chu, 36 USPQ2d 1089, 1094 (Fed. Cir. 1995). A *prima facie* case of obviousness is established only when this burden is met.

In the case of In re Lee, 61 USPQ2d 1430 (Fed. Cir. 2002), the Federal Circuit stated: "This factual question of motivation is material to patentability, and [can] not be resolved on subjective belief and unknown authority." Id. at 1434.

The Court of Appeals for the Federal Circuit has made clear that motivation to combine references must be found in the record, and that it is impermissible hindsight for the Examiner to use the motivation stated in Applicants' own disclosure as a blueprint to reconstruct the claimed invention from the prior art. See Interconnect Planning Corp. v. Feil, 227 USPQ 543 (Fed. Cir. 1985); In re Fine, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988); In re Gorman, 18 USPQ 2d 1885, 1888 (Fed. Cir. 1991); Al-Site Corp. v. VSI International, Inc., 50 USPQ2d 1161, 1171 (Fed. Cir. 1999).

A patentable invention may arise from a combination of elements found in the prior art. It is therefore not sufficient for the Examiner merely to identify individual components of an invention in multiple references. E.g., Ruiz v. A.B. Chance Co., 57 USPQ2d 1161, 1167 (Fed. Cir. 2000). The Examiner must demonstrate that a skilled artisan, with no knowledge of Applicants' claimed invention, would have selected the components for combination in the manner claimed. In re Kotzab, 55 USPQ2d 1313, 1316-18 (Fed. Cir. 2000). It is not sufficient for the Examiner to assert that separate elements of the claimed invention exist in the prior art, or that the elements in different references *could* be combined, or that there is an apparent need for combination of the elements, or that elements may be substitutes for one another. Ruiz v. A.B. Chance Co., 57 USPQ2d at 1167. To establish a *prima facie* case of unpatentability, the Examiner must provide evidence showing a reason, suggestion or motivation to combine.

The Examiner has failed to provide evidence showing a reason, suggestion or motivation to combine a Salo sensor with a Prochazka system. The Examiner suggested combining a Salo sensor with a Prochazka system would simplify the external electronics of the monitoring system by eliminating the need for the external controller to produce a control signal, but there is no support in the record for such a

suggestion. Nothing in Prochazka or Salo suggests that external electronics would benefit from simplification.

Furthermore, Prochazka and Salo fail to disclose one of more elements recited in claims 1-5. Even if a Salo sensor were to be combined with a Prochazka system, Applicants' claimed invention would not result.

Neither Prochazka nor Salo discloses an external sensor module transmitting collected physiological data signals to the IMD, as recited in claim 1. On the contrary, Prochazka discloses transmitting "commands" to the implanted stimulator (col. 6, lines 49-51), rather than physiological data. Salo describes an external programmer, not a sensor, controlling a pacemaker, but does not disclose transmission of physiological data (col. 6, lines 32-34; FIG. 7). To the extent that Salo discloses an external sensor communicating with a pacemaker, *both* the sensor and the pacemaker are external to the patient, and the pacemaker is not an IMD (col. 6, lines 37-40, FIG. 8).

Prochazka and Salo also fail to teach or suggest the IMD processor processing the physiological data to produce therapy delivery control signals in implementation of dynamic closed loop self monitoring therapy delivery, as recited in claim 1. In the Prochazka and Salo systems, no implanted device receives physiological data, and consequently no implanted device processes physiological data in implementation of dynamic closed loop self monitoring therapy delivery, as recited in claim 1.

As to claim 5, the Examiner acknowledged that the Prochazka was a joint movement sensor, rather than one of the sensors recited in claim 5. The Examiner declared, however, that change of the type of sensor would be an obvious design choice.

The Examiner's assertion that changing the type of sensor would have been an "obvious design choice" is incorrect as a matter of law. First, it applies an incorrect legal standard. In a proper obviousness determination, the prior art must give a reason or motivation for making the claimed invention. *E.g.*, In re Chu, 36 USPQ2d at 1094; In re Oetiker, 24 USPQ2d at 1446. The combination of elements from non-analogous sources, in a manner that reconstructs the Applicants' invention only with the benefit of hindsight, is insufficient to support a *prima facie* case of obviousness. In re Oetiker, 24 USPQ2d at 1446. Where the prior art does not teach that references should be

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combined to produce the claimed invention, the Examiner cannot cure this deficiency by using words such as "design choice" or "design alternative." In re Chu, 36 USPQ2d at 1094-95.

A bare assertion that an element of a claim is an "obvious design choice" does not support a *prima facie* case of unpatentability. It is merely a conclusory statement, unsupported by the record, and cannot support a *prima facie* case of unpatentability. In re Lee, 61 USPQ2d at 1434-35; In re Dembiczak, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicants' claims 1-5 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

Tockman in view of Kopotic

The Examiner rejected claim 3 under 35 U.S.C. § 103(a) as being unpatentable over Tockman in view of Kopotic (US 6,470,199). The Examiner asserted that Tockman discloses the claimed invention except for the pulse oximeter being a sock. According to the Examiner, Kopotic teaches oximeter positioning using a sock for the purpose of securing the oximeter in place. The Examiner declared that it would have been obvious to one having ordinary skill in the art at the time of the invention to have used a Kopotic sock to secure an oximeter in a Tockman system in order to avoid skin and tissue damage and to avoid misalignment of the emitter and detector of the oximeter.

Applicants respectfully traverse the rejection. Applicants incorporate arguments made above that the Examiner bears the burden of establishing a *prima facie* case of obviousness, and must have support in the record for a motivation to combine features of one reference with features from another. The Examiner may not defeat patentability merely by identifying individual components of an invention in multiple references. The Examiner has failed to provide evidence showing a reason, suggestion or motivation to combine a Kopotic sock with a Tockman system. Contrary to the Examiner's assertion, neither Kopotic nor Tockman discuss avoiding tissue damage, and nothing in Tockman

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suggests that there is any problem with pulse oximeter 50 that the Kopotic sock can solve.

Applicants also incorporate arguments made above that show that Tockman does not disclose elements of the claimed invention, contrary to the Examiner's assertion. In particular, Tockman fails to disclose an external sensor module transmitting collected physiological data signals to the IMD, as recited in claim 3. The Tockman sensors themselves do not transmit physiological data signals to the IMD. In fact, the Tockman sensors themselves do not transmit signals of any kind to the IMD.

For at least these reasons, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicants' claim 3 under 35 U.S.C. § 103(a). Withdrawal of this rejection is requested.

Claim Objection

The Examiner objected to claims 1-5 because the Examiner felt that the words "of dynamic" should be --dynamic--. Applicants respectfully disagree with the Examiner. The words "implementation of dynamic closed loop self monitoring therapy delivery" read correctly, and the words "implementation dynamic closed loop self monitoring therapy delivery" would not read correctly.

Applicants have stricken a superfluous instance of the word "of" from claim 1, changing the words "of of dynamic" to --of dynamic--. Perhaps deletion of a superfluous instance of the word "of" is what the Examiner had in mind.

CONCLUSION

Applicants respectfully assert that, following entry of the instant Amendment, all pending claims (i.e., claims 1-5 and 8-13) of the present application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims so that the invention herein claimed may pass to timely issuance as U.S. Letters Patent. Please charge any additional fees or credit any overpayment to

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deposit account number 13-2546. The Examiner is invited to telephone the below-
signed attorney to discuss this application.

Respectfully submitted,

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